



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,461	03/21/2005	Jong-Woo Kim	26681U	4853
20529	7590	12/06/2006	EXAMINER	
NATH & ASSOCIATES				NOLAN, JASON MICHAEL
112 South West Street				
Alexandria, VA 22314				
ART UNIT		PAPER NUMBER		
		1626		

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/528,461	KIM ET AL.	
	Examiner	Art Unit	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 21 March 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/21/2005

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

**Claims 1-3** are currently pending in the instant application; of which, all have been amended.

### ***Priority***

Receipt of 10-2002-006-1994, filed on 10/11/2002 in the Republic of Korea, submitted under 35 U.S.C. §§ 119(a)-(d) is acknowledged; which papers have been placed of record in the file. Claim for priority in the Oath is acknowledged.

### ***Information Disclosure Statement***

Applicants' information disclosure statement (IDS), filed on March 21, 2005 has been considered. Please refer to Applicants' copy of the 1449 submitted herein.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-3** are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claims recite the term "derivative" and the scope of this term is unclear, such that it fails to define the metes and bounds of its limitation. Derivatives may be interpreted in different ways. For example, a derivative

of the compound represented by formula I may be a pharmaceutically acceptable salt. On the other hand, a derivative of formula I could be an ester of the acid at the 3-position on the pyridine ring. The specification fails to define the term "derivative", therefore the Examiner suggests rewriting **Claims 1-3** such that the invention refers to "The compound represented by the formula I."

**Claim 3** is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for compositions for the *treatment* of hepatitis C, does not reasonably provide enablement for compositions for the "*prevention*" of hepatitis C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue'."

*In re Wands*, 8 USPQ2d 1400 (1988), discusses the following factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph:

1. *The nature of the invention;*
2. *The state of the prior art;*
3. *The predictability or lack thereof in the art;*
4. *The amount of direction or guidance present;*
5. *The presence or absence of working examples;*
6. *The breadth of the claims;*
7. *The quantity of experimentation needed; and*
8. *The level of skill in the art*

each of which is discussed in turn below.

***The nature of the invention***

The nature of the invention is compounds and compositions of Formula I, the process for preparing these compounds. The nature of this rejection is the intended use language in **Claim 3**: "prevention of hepatitis C." When evaluating the scope of a claim, every limitation in the claim must be considered. Therefore, although **Claim 3** is not a method claim, the specification must still provide support for the recited intended use.

***The state of the prior art and the predictability or lack thereof in the art***

The state of the prior art, namely pharmacological art, involves screening *in vitro* and *in vivo* to determine if the compounds exhibit desired pharmacological activities, which are then tested for their efficacy on human beings. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant claimed invention is highly unpredictable as discussed below.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly unpredictable since one skilled in the art would recognize that a group of compounds and compositions may provide a treatment for hepatitis C, but it does not mean that the same group of compounds and compositions may prevent hepatitis C.

***The amount of direction or guidance present and the presence or absence of working examples***

There is no direction or guidance provided which supports Applicant's claimed method for the prevention of hepatitis C as indicated. The direction or guidance present in Applicants' Specification for a method of using the compositions of Formula I to treat hepatitis C is found throughout. However, the specification states: "So far, no one has actually found vaccine or therapeutics that is very effective for HCV." (p. 4, ll. 25-26) and "So far, no one actually developed an antiviral agent for treating hepatitis C by suppressing the replication of HCV." (p. 6, ll. 13-15). Therefore, it would be necessary to see evidence that the composition can prevent hepatitis C within the specification in order to justify the invention as claimed. The examples present in the specification (p. 11-13) only establish the compositions of formula I as inhibitors on recombinant HCV RNA Polymerase *in vitro*.

***The breadth of the claims, quantity of experimentation, and level of skill in the art***

Claim 3 is drawn to "A pharmaceutical composition for the treatment and prevention of hepatitis C..." In order to prevent a disease, one would need to precisely identify those subjects likely to acquire such a disease, administer Applicant's claimed invention, and then demonstrate that if the identified subject did not develop the disease, such an effect was the direct result of administration of the claimed invention.

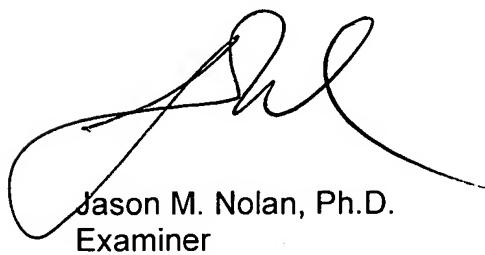
Because of the aforementioned reasons, a person of skill in the art could not practice the claimed invention herein, or a person of skill in the art could practice the

Art Unit: 1626

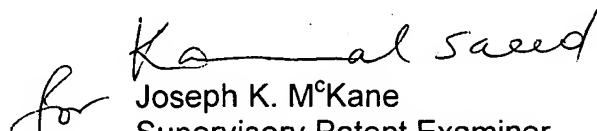
claimed invention herein only with undue experimentation and with no assurance of success. Deleting the word "prevention" in **Claim 3** will overcome this rejection.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M<sup>c</sup>Kane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jason M. Nolan, Ph.D.  
Examiner  
Art Unit 1626



for **Komal Saeed**  
Joseph K. M<sup>c</sup>Kane  
Supervisory Patent Examiner  
Art Unit 1626  
Date: November 28, 2006